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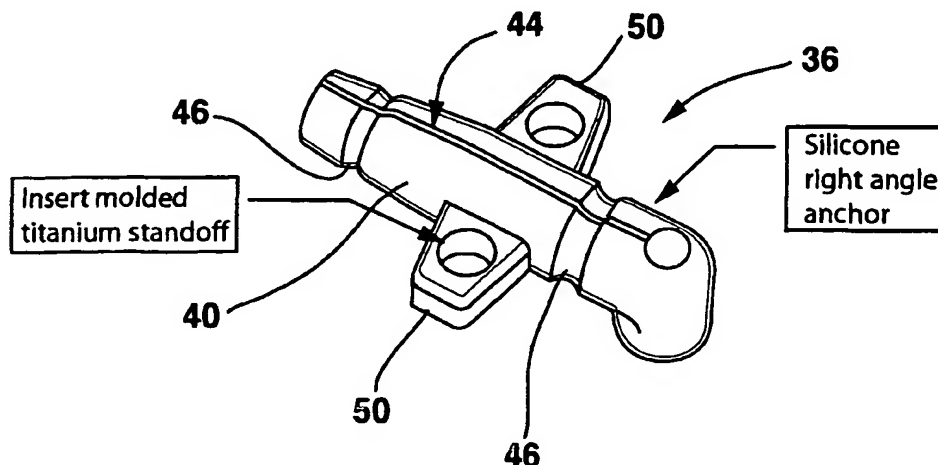
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10/128,708 23 April 2002 (23.04.2002) **US**
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Declaration under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK,*

[Continued on next page]

(54) Title: **CATHETER ANCHOR SYSTEM**



(57) Abstract: ABSTRACT A catheter system (30) for intracranial infusion of therapeutic substances to a patient. An anchor (36) formed of generally flexible, elastomeric material is used to mount the catheter (34) to the outer surface of the skull of the patient. The anchor (36) has a through hole (48) for receiving the catheter (34), a channel (42), extending substantially from the through hole (48), into which a portion of the catheter (34) may be inserted to retain the portion substantially parallel to the surface of the skull, and at least one flange (50) for engaging the outer surface of the skull. At least one substantially rigid standoff (52) is provided in the flange (50), with the standoff (52) having an opening for receiving a fastener to fasten the anchor (36) to the skull.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

CATHETER ANCHOR SYSTEM

This application relates generally to implantable catheters, and more particularly to an anchor and method of use for mounting a catheter within a patient, for example, to the skull.

Sometimes therapeutic substances, such as drugs, biologics, etc., are infused intraparenchymally or intracerebroventricularly to treat brain disorders, such as malignancies or neurodegenerative diseases. Co-assigned US patent applications Serial Nos. 09/540,444, filed March 31, 2000, and 09/625,751, filed July 26, 2000, (see, also WO 2002/07810) disclose catheters that are particularly well suited for intraparenchymal or intraventricular convection-enhanced infusion of therapeutic substances. As used herein, "IPA" means intraparenchymal, "ICV" means intracerebroventricular, and "intraventricular" and "ventricles" refer to cerebroventricles.

Previously, intracranial catheters have been anchored to the periosteum, which is a fibrous membrane covering the surface of bone. The periosteum has not provided as much stability as desired, and movement of the catheter anchor may result in changes in the location of the catheter tip.

Embodiments of this invention include a catheter system for intracranial delivery, such as intraparenchymal or ventricular delivery, of therapeutic substances to a patient. Embodiments of this system are adapted to anchor a flexible catheter in position relative to the skull for infusion of therapeutic substances, while allowing the anchor to be soft and pliable and thereby less likely to cause skin erosion. These embodiments are further adapted to be anchored to the skull bone rather than fragile periosteum.

In a first embodiment, the catheter system generally comprises an elongate catheter (e.g., formed of silicone or polyurethane) having a lumen and at least one drug delivery orifice in fluid communication with the lumen, and an anchor formed of generally flexible, elastomeric material for mounting the catheter to the outer surface of the skull of the patient. The anchor has a through hole for receiving the catheter, and a channel extending substantially from the through hole. A portion of the catheter may be inserted into the channel to retain the portion substantially parallel

to the surface of the skull. At least one flange is provided for engaging the outer surface of the skull. At least one substantially rigid standoff is mounted in the flange, with the standoff having an opening for receiving a fastener to fasten the anchor to the skull.

Most preferably, the anchor is adapted to flex and comply with adjacent tissue. For
5 example, the generally flexible, elastomeric material of the anchor may comprise silicone.

Preferably, two flanges are provided on the anchor, with at least one standoff mounted in
each flange. For example, the standoffs may be insert molded in the flanges of the anchor. The
standoffs may be formed of titanium or titanium alloy. The standoffs are preferably substantially
annular and have an undercut or circumferential channel helping to retain the standoff in the
10 flange.

Also, preferably, the anchor has a body in which the through hole and channel are formed,
with the body being generally elongate and coaxial with the channel. The body extends in a
direction generally perpendicular to the through hole and openings of the standoffs, and the
flanges extending substantially in opposite directions substantially perpendicular to the body. The
15 channel is substantially perpendicular to the through hole.

In certain embodiments of the invention, an anchor clip is also provided, which is adapted
to be fastened to the outer surface of the skull to stabilize the catheter relative to the skull. The
anchor clip engages the body of the anchor adjacent the through hole. For example, the anchor
clip may be generally V-shaped having two legs each having a free end and a joined end joined
20 with the other leg. The free end of each leg has an opening for receiving a fastener to mount the
anchor clip to the skull. The anchor clip also having a slot adjacent the joined ends of the legs for
engagement with the anchor to stabilize the anchor.

The catheter system is preferably used in combination with an implantable therapeutic
substance infusion device, such as an implantable drug pump. The catheter may be directly or
25 indirectly connected with the implantable therapeutic substance infusion device for infusion of
therapeutic substance from the implantable therapeutic substance infusion device through the
lumen and orifice(s) of the catheter. Indirect connection includes without limitation intermediate
connectors or tubing sections.

In another aspect of the invention, a method of implanting the catheter system comprises: (a) inserting the catheter into the parenchyma or a ventricle; (b) mounting the anchor on the catheter and the skull of a patient to retain the catheter in position; and (c) infusing a therapeutic agent into the parenchyma or a ventricle for treatment of brain tissue.

5 Preferably, the anchor is mounted on the catheter and the skull of a patient to retain the catheter in position by: (a) inserting the catheter into the through hole of the anchor; (b) sliding the anchor along the catheter into engagement with the skull; (c) inserting a fastener through each opening of the standoff to fasten the anchor to the skull; and (d) placing the anchor in the channel. The catheter may also be sutured in the channel.

10 Figure 1 illustrates the use of an embodiment of the catheter system in combination with an implantable therapeutic substance infusion device (e.g., drug pump).

Figure 2 is a side view of an embodiment of the catheter system.

Figure 3 is a side view of a catheter with portions cut away to illustrate details.

Figure 4 is a perspective view of an embodiment of an anchor of the system.

15 Figure 5 is another perspective view of an anchor.

Figure 6 is a side elevation of the anchor of figures 4-5 with a portion cut away to illustrate details of an embodiment of a rigid standoff.

Figures 7 and 8 are perspective and cross sectional views of a standoff of figure 6.

Figure 9 is a photograph of an embodiment of the catheter system being implanted.

20 Figures 10-21 are illustrations showing an embodiment the catheter system and a method of implanting the catheter system.

A catheter system 30 of the invention is shown in figure 1 in combination with an implantable therapeutic substance infusion device, such as an implantable drug pump 32 ("IDP"). Figure 1 illustrates use of the catheter system to infuse therapeutic substances stored in the

reservoir of the IDP 32 into the parenchyma but the system could also be used to infuse such substances into other regions, such as cerebroventricles.

Figure 2 illustrates further details of the catheter system 30, which comprises the catheter 34, anchor 36 and stylet 38. The stylet 38 provides sufficient rigidity to facilitate handling the catheter 34, which is preferably very soft and flexible. The stylet 38 is removed after the catheter 34 has been moved into position. Various markings may be provided along the catheter 34 to facilitate positioning and implantation.

A preferred catheter 34 for use in the catheter system is the catheter disclosed in US patent application Serial No. 09/625,751, filed July 26, 2000, which is incorporated herein by reference. Figure 3 illustrates details of a preferred embodiment of the catheter in which a multiplicity of very small diameter orifices or openings are provided through the wall of the catheter. The preferred orifice arrangement relative to the diameter of the catheter lumen ensures that fluid is delivered fairly evenly across the orifices. The catheter 34 may be formed, for example, of silicone or polyurethane.

As illustrated in figures 4-6, a preferred embodiment of the anchor 36 comprises a soft, pliable elongate body 40 having a generally circular cross section. A longitudinal channel 42 is provided in the body 40 with a slot 44 open along the top of the channel 42 to allow a catheter 34 to be inserted through the slot 44 into the channel 42. The catheter-receiving channel 42 is sized, configured and adapted to receive the catheter 34 to hold the catheter 34 generally parallel or tangent to the surface of the skull. Two annular channels 46 may be provided on the body 40 for receiving sutures (not shown) to further lock the catheter 34 in the channel. The anchor 36 is preferably formed of an elastomeric material, such as silicone or polyurethane.

A through hole 48 is provided adjacent the proximal end of the body 40 of the anchor 36. The catheter 32 may be inserted into, and the anchor 36 slide along the catheter 32, to position the anchor 36 against the skull. Alternatively, the anchor 36 may be positioned adjacent the burr hole and the catheter 32 slide through the through hole 48 of the anchor 36 into position. In yet another alternative, the anchor 36 may be designed, for example, by the addition of a slit (not

shown) to allow the anchor 36 to be attached to the catheter 32 in the lateral or radial direction rather than, or in addition to, being slide longitudinally relative to the catheter 32.

5 The through hole 48 and channel 42 are substantially oriented at right angles to one another. The longitudinal channel 42 and through hole 48 are connected so that the catheter 32 can be bent at about a right angle to be held in the channel 42 in an orientation generally parallel or tangent to the surface of the skull.

10 At least one flange or tab, but preferably two flanges 50 extend in generally opposite directions from the body 40. The flanges 50 are integrally molded as one continuous piece with the body 40. The flanges 50 are set back from the proximal end of the body 40 (i.e. the end with the through hole 48) so that the flanges 50 may rest on bone adjacent a burr hole (see, e.g., figure 13) with the through hole 48 held over the burr hole. The anchor 36 maintains the through hole 48 substantially at a predetermined orientation and location relative to the skull and burr hole. For example, the through hole 48 is maintained substantially at a perpendicular orientation relative to the plane of the burr hole.

15 At least one generally rigid standoff 52 is provided on each flange 50 as illustrated in figures 4-8. The standoffs 52 are adapted to receive a fastener, such as a surgical screw, to fasten the anchor 36 to bone. The standoffs 52 are formed of material that is much more rigid than the soft, pliable silicone preferred for the anchor 36. Examples of suitable materials include titanium and titanium alloy, although other materials could alternatively be employed. Each standoff 52 is generally cylindrical with an undercut or annular channel provided along the circumferential surface to help lock the standoff 52 on the flange 50, for example, by insert molding the standoff 20 52. Alternatively, the standoffs 52 can be fixed in the flanges 50 by other suitable techniques, including without limitation bonding. Each standoff 52 includes a central bore or opening for receiving a fastener, such as a screw.

25 The through hole 48 constitutes one preferred embodiment of an orienting means for slidably receiving the catheter and orienting the catheter relative to the parenchyma. The longitudinally-extending, catheter-receiving channel 42 constitutes one preferred embodiment of a

means, generally adjacent the orienting means, for laterally receiving the catheter to retain a portion of the catheter substantially parallel to the surface of the skull.

The flanges 50 constitute a preferred embodiment of a generally flexible skull-engaging means for engaging the outer surface of the skull. The standoffs 52 constitute a preferred
5 embodiment of a substantially rigid means in the skull engaging means for receiving a fastener to fasten the anchor 36 to the skull.

An optional anchor clip 54 (see, e.g., figures 14-17) may also be provided, which is adapted to be fastened to the outer surface of the skull to stabilize the catheter 32 relative to the skull. The anchor clip 54 engages the body 40 of the anchor 36 adjacent the through hole 48. The
10 body 40 of the anchor 36 preferably includes a downwardly extending annular portion coaxial with the through hole which may be received in a retaining slot 56 in the anchor clip 54. Suitable materials for the anchor clip 54 include, for example, polysulfone.

Most preferably, the anchor clip 54 is generally V-shaped, with two legs 58 each having a free end and a joined end forming an apex of the clip 54 with the other leg. The free end of each
15 leg has an opening 60 for receiving a fastener to mount the anchor clip 54 to the skull. The retaining slot 56 is formed at the apex of the clip 54 adjacent the joined ends of the legs. The retaining slot 56 engages the anchor 36 to stabilize the anchor 36.

Figures 10-21 illustrate various aspects of a preferred method of implanting a catheter anchor system. As illustrated in figure 10, this method includes (a) forming (cutting, drilling,
20 etc.) a burr hole through the skull of a patient, and (b) inserting a catheter into the parenchyma or ventricle of the patient. The catheter 32 is preferably soft and conformable, and rigidity is provided temporarily by a rigid stylet to facilitate controlled insertion. In addition, imaging and various guidance means, such as stereotactic or non-stereotactic frames may be employed. After the catheter 32 is in position, the stylet is removed as illustrated in figure 11.

25 A catheter anchor 36 is then placed on the catheter 34 and slide down the catheter 32 into position against the skull as illustrated in figures 12 and 13. Alternatively, the anchor 36 may be positioned adjacent the burr hole and the catheter 32 slide through the through hole 48 of the

anchor 36 into position. Figure 13 illustrates screwing surgical screws through the standoffs 52 to fasten the anchor 36 to the skull.

5 An optional anchor clip 54 is attached to the anchor 36 and skull as illustrated in figures 14 and 15 to help stabilize the proximal end of the anchor 36 to help stabilize the catheter 34 relative to the skull.

The catheter 34 is then laid down through the top slot of the anchor 36 into the catheter-receiving channel 42, and sutures may be employed to retain the catheter 34 in the channel 42 as illustrated in figures 16 and 17.

10 Figures 18-21 illustrate use of a connector sleeve, connector pin, proximal tubing and sutures to connect the catheter 34 to a implantable drug pump or other implantable therapeutic substance infusion device.

15 Thus, embodiments of the catheter anchor system and method are disclosed. One skilled in the art will appreciate that the present invention can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the present invention is limited only by the claims that follow.

Claims:

1. A catheter system (30) for intracranial delivery of therapeutic substances to a patient, the system (30) comprising:
 - an elongate catheter (34) having a lumen and at least one drug delivery orifice in fluid communication with the lumen;
 - an anchor (36) formed of generally flexible, elastomeric material for mounting the catheter (34) to the outer surface of the skull of the patient, the anchor (36) having:
 - a through hole (48) for receiving the catheter (34),
 - a channel (42), extending substantially from the through hole (48), into which a portion of the catheter (34) may be inserted to retain the portion substantially parallel to the surface of the skull;
 - at least one flange (50) for engaging the outer surface of the skull; and
 - at least one substantially rigid standoff (52) mounted in the flange (50), the standoff (52) having an opening for receiving a fastener to fasten the anchor (36) to the skull.
2. The catheter system (30) of claim 1 in which the at least one flange (50) comprises two flanges (50) extending in opposite directions from the channel (42), the at least one substantially rigid standoff (52) comprising at least one standoff (52) mounted in each flange (50).
3. The catheter system (30) of claim 2 in which the anchor (36) has a body (40) in which the through hole (48) and channel (42) are formed, the body (40) being generally elongate and coaxial with the channel (42), the body (40) extending in a direction generally perpendicular to the through hole (48) and openings of the standoffs (52), the flanges (50) extending substantially in opposite directions substantially perpendicular to the body (40).
4. The catheter system (30) of any of claims 1-3 in which the channel (42) is substantially perpendicular to the through hole (48).

5. The catheter system (30) of any of claims 1-4 in which the generally flexible, elastomeric material comprises silicone.

5 6. The catheter system (30) of any of claims 1-5 in which the anchor (36) is adapted to flex and comply with adjacent tissue.

7. The catheter system (30) of any of claims 1-6 in which the standoffs (52) are insert molded in the flanges (50) of the anchor (36).

10

8. The catheter system (30) of any of claims 1-7 in which the standoffs (52) are formed of titanium or titanium alloy.

15

9. The catheter system (30) of any of claims 1-8 in which the standoffs (52) are substantially annular and have an undercut or circumferential channel helping to retain the standoff (52) in the flange (50).

20

10. The catheter system (30) of any of claims 1-9 further comprising an anchor clip (54) adapted to engage the body (40) of the anchor (36) adjacent the through hole (48), the anchor clip (54) being adapted to be fastened to the outer surface of the skull to stabilize the catheter (34) relative to the skull.

25

11. The catheter system (30) of claim 10 in which the anchor clip (54) is generally V-shaped having two legs (58) each having a free end and a joined end joined with the other leg, the free end of each leg (58) having an opening (60) for receiving a fastener to mount the anchor clip (54) to the skull, the anchor clip (54) having a slot (56) adjacent the joined ends of the legs (58) for engagement with the anchor (36) to stabilize the anchor (36).

30

12. The catheter system (30) of claim 10 or 11 in which the anchor clip (54) is formed of polysulfone

13. The catheter system (30) of any of claims 1-12 in which the catheter (34) is formed of silicone or polyurethane.

5 14. A combination of the catheter system (30) of any of claims 1-13 with an implantable therapeutic substance infusion device (32), the catheter (34) being directly or indirectly connected with the implantable therapeutic substance infusion device (32) for infusion of therapeutic substance from the implantable therapeutic substance infusion device (32) through the lumen and orifice(s) of the catheter (34).

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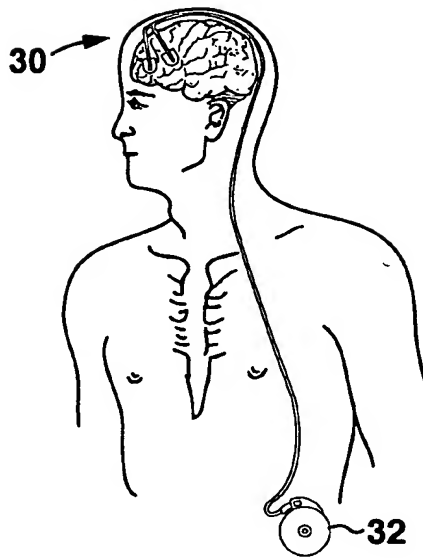


FIG. 1

CATHETER TIP CLOSE UP



FIG. 3

34

INTRAPARENCHYMAL CATHETER

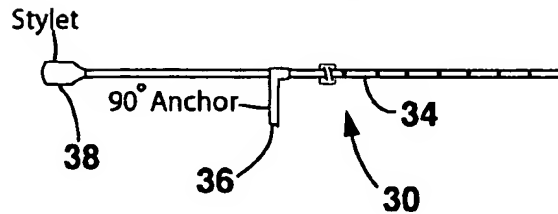


FIG. 2

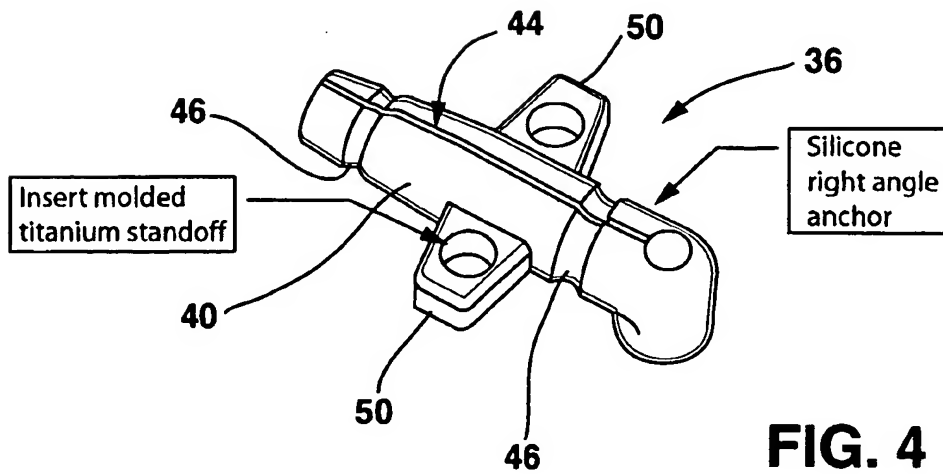


FIG. 4

FIG. 5

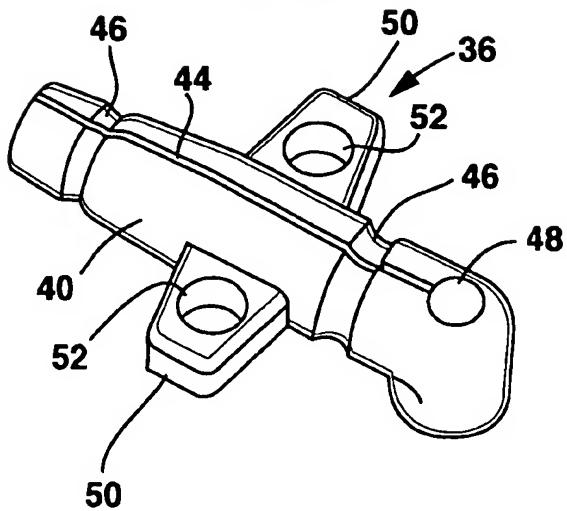


FIG. 7

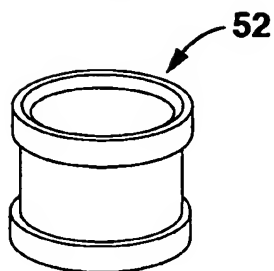


FIG. 8

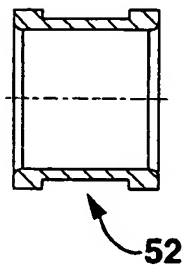


FIG. 6

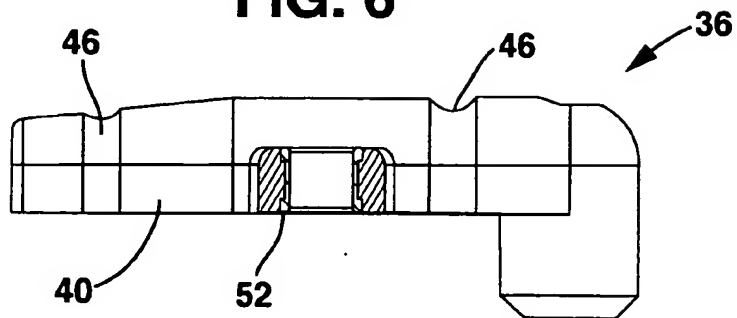
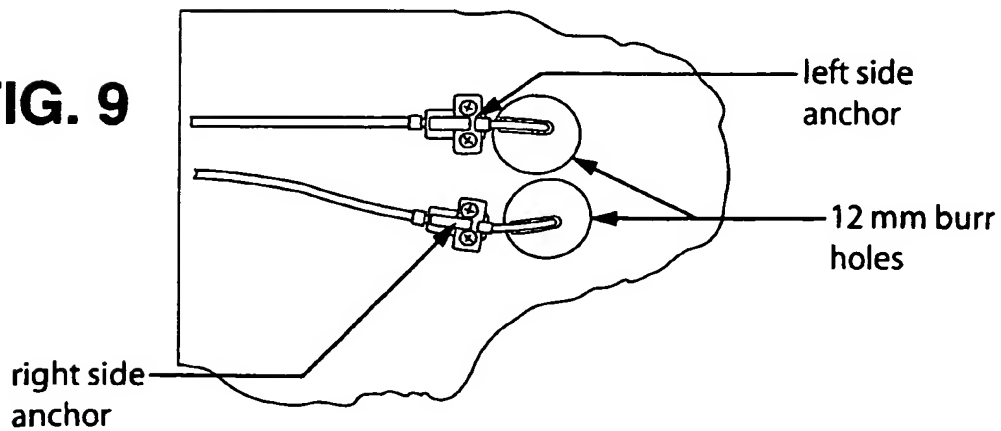


FIG. 9



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FIG. 10

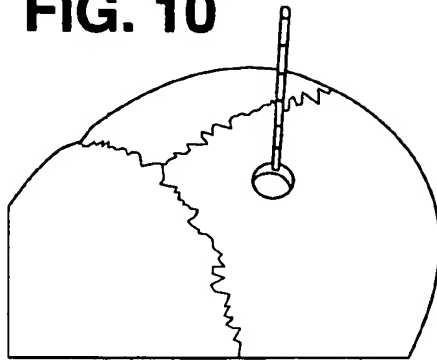


FIG. 11

Remove Stylet

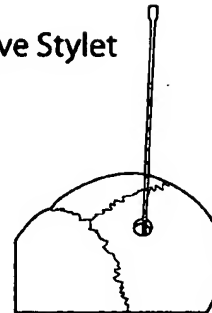


FIG. 12

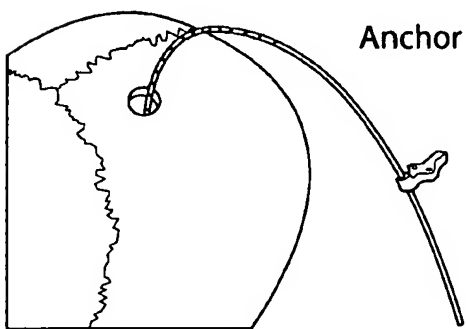


FIG. 13

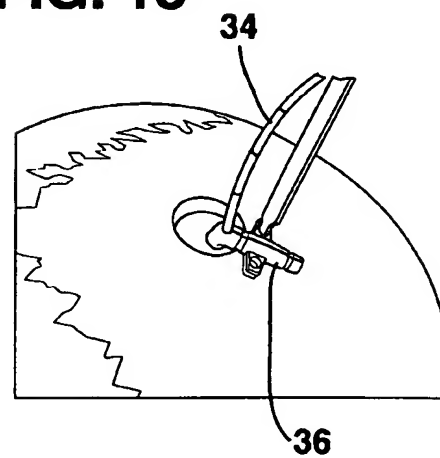


FIG. 14

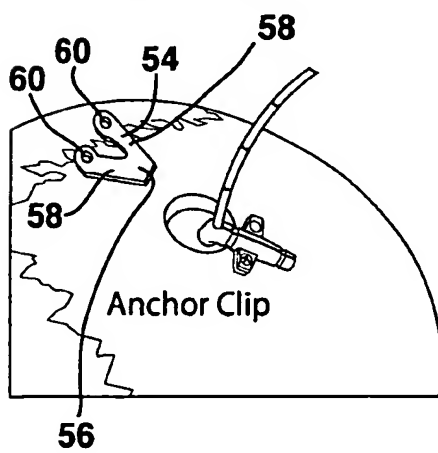
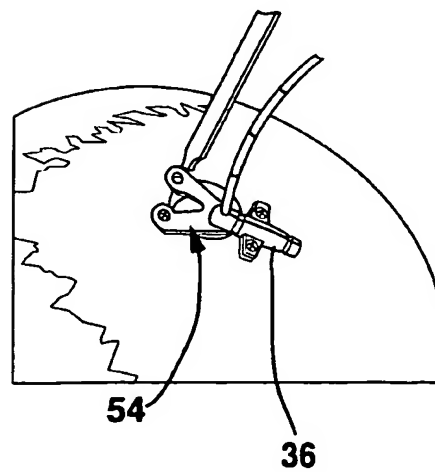


FIG. 15



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FIG. 16

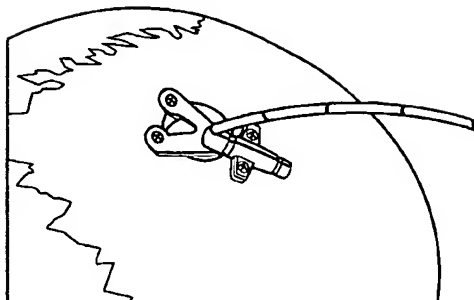


FIG. 17

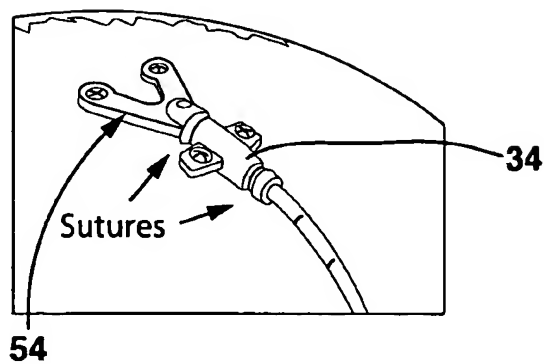


FIG. 18

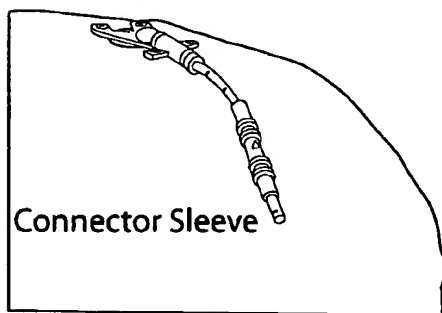


FIG. 19

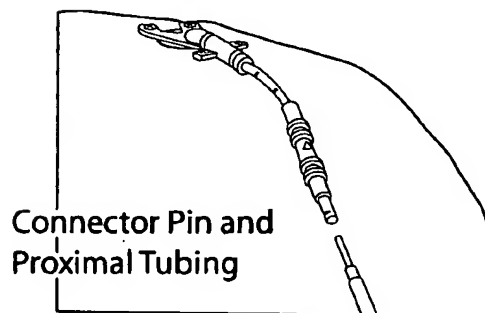


FIG. 20

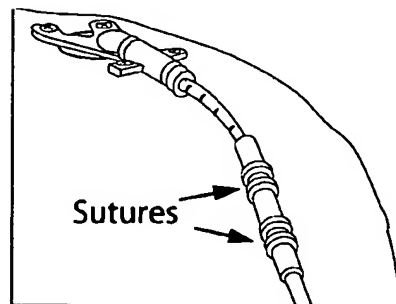
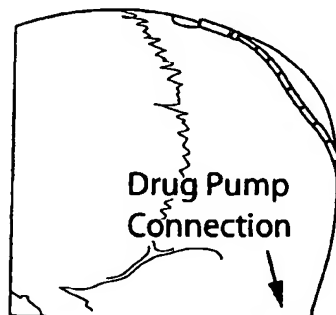


FIG. 21



INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 03/10087

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61M5/00 A61M25/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 435 174 A (REDMOND RUSSELL J ET AL) 6 March 1984 (1984-03-06)	1-9, 13, 14
A	the whole document ---	10-12
Y	WO 02 13714 A (PARMER KARI ;DAVID JOHN (US); MILLER THOMAS I (US); IMAGE GUIDED N) 21 February 2002 (2002-02-21)	1-9
A	abstract; figures 2,8,13-17 ---	10-14
Y	FR 2 806 918 A (MEDTRONIC INC) 5 October 2001 (2001-10-05) cited in the application page 6, line 8 -page 7, line 9 page 12, line 11 -page 13, line 9; figures 1,2 ---	13,14
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
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Date of the actual completion of the international search

3 July 2003

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